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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/040,161	03/17/98	KORNBLITH	F 2509-980363

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HM32/0629

EXAMINER	
BITOMER, R	
ART UNIT	PAPER NUMBER
1623	3
DATE MAILED:	
06/29/98	

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No. 09/040,161	Applicant(s) Kornblith
Examiner Ralph Gitomer	Group Art Unit 1623



Responsive to communication(s) filed on Mar 17, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 13-19 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 13-19 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The preliminary amendment received 3/17/98 has been entered and claims 13-19 are currently pending in this application. The amended title and abstract are acceptable.

5 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple 10 assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15 A timely filed terminal disclaimer in compliance with 37 CFR 1.321[®] may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

20 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25 Claims 13-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,728,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to multicellular particulates and the claims of '541 are directed to 1 mm³ particulates specifically.

Claims 13-19 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The feature of the size of the particulates is critical or essential to the practice of the invention, but not included in the 5 claim(s) is not enabled by the disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

On page 5 lines 15-16 of the present specification, "Preferably but not necessarily, the tumor particulates each measure 1 mm³." It would appear the claimed invention would not work unless the particulates were of a certain size and the 10 specification teaches only this one size.

Claims 13-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 15 particles of a specific size, does not reasonably provide enablement for particles of any size. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

20 In claim 13 and all occurrences, the terms "cohesive multicellular particulates" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which size would work in the instant invention.

"Cohesive multicellular particulates" reads on an entire organ to two cells, neither of which are likely to work in the claimed invention.

The entire scope of the claims has not been enabled because:

- 5 1. Quantity of experimentation necessary would be undue because of the large number of sizes claimed.
2. Amount of direction or guidance presented is insufficient to predict which sizes encompassed by the claims would work.
- 10 3. Presence of working examples are only for a single size and extension to other sizes has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most sizes are not effective for the claimed functions.
- 15 6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of sizes.
8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 13-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 In claim 13, "cohesive multicellular particulates" is not understood as so what the specimen is separated into. Note the expression reads on no separating to forming two cell particulates.

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knodel, can be reached on (703) 308-15 4311. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose 20 telephone number is (703) 308-1234.

R. Gitomer

25 Ralph Gitomer
Primary Examiner
Group 1623

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200